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2.0 510(k) SUMMARY FOR THE FACIAL RECONSTRUCTIVE MESH

Submission Date: October 16, 2006

JUL 10 2007

Submitter Information:

Company Name: Becker and Associates Consulting, Inc.

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Contact Person: Campbell Tuskey
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Device Information:

Trade Name: Facial Reconstructive Mesh (FRM)

Common Name: Surgical Mesh

Classification Name: 21 CFR § 878.3300

Classification Code: FTL

Device Class: Class II

Predicate Device(s):

Trade Name: Mersilene Polyester Fiber Mesh
Manufacturer: Ethicon, Inc.
K Number: K851086
Product Code: FTM

Trade Name: Permacol™ Crosslinked Porcine Dermal Collagen Surgical Mesh
Manufacturer: Tissue Sciences Laboratories PLC
K Number: K013625
Product Code: FTM

Trade Name: Gore-Tex SAM Facial Implant with Introducer
Manufacturer: W.L. Gore and Associates, Inc.
K Number: K952898
Product Code: FTL

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Trade Name:	Bard Composite Prosthesis
Manufacturer:	Davol, Inc.
K Number:	K971745
Product Code:	FTL

Device Description: The FRM is a non-absorbable, inert, sterile, porous, surgical mesh composed of reinforcing woven polyester fabric, silicone elastomer and expanded polytetrafluoroethylene (ePTFE). This polymeric mesh is available in a range of lengths and widths to accommodate the surgical application.

Intended Use: The FRM is intended for use in the reinforcement of soft tissue where weakness exists. It is placed by a surgeon into the tissue by conventional surgical techniques during plastic or reconstructive surgery.

Indications for Use: The FRM is intended for use in plastic and reconstructive surgery of the face and head to provide soft tissue repair or reinforcement.

Contraindications:
- Dermal placement
- Cosmetic lip filler

Comparison to Predicate Device: The FRM has the same intended use and technological characteristics as the predicate devices. Slight differences in design and performance from the cited predicates do not affect either the safety and/or effectiveness of the FRM for its intended use. The safety and effectiveness evaluations based on biocompatibility and biomechanical performance data provided in this 510(k) demonstrate that the FRM is substantially equivalent to the cited predicate devices.

Conclusion: The results of these evaluations of the FRM support the conclusion that it is safe and effective for its intended use and that it is substantially equivalent to the cited predicate device(s) with regards to its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2007

Evera Medical, Inc.
% Mr. Randy Kesten
Chief Technical Officer
353 Vintage Park Drive, Suite F
Foster City, California 94404

Re: K063154
Trade/Device Name: Facial Reconstructive Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 12, 2007
Received: June 14, 2007

Dear Mr. Kesten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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1. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K063154

Device Name: Facial Reconstructive Mesh

Indications for Use:

The Facial Reconstructive Mesh is intended for use in plastic and reconstructive surgery of the face and head to provide soft tissue repair or reinforcement.

Contraindications:

- Dermal placement
- Cosmetic lip filler

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he / she practices to use or order the use of the device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation~~ (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063154